

REMARKS

In the instant Action, claims 2-22, 26, 30-34 and 38 are listed as pending and all claims are finally rejected. Claims 2-16, 20-21, 30 and 33-34 are canceled in this reply. Claims 23-25, 27-29, 35-37 and 39-40 were previously canceled. In summary, claims 17-19, 22, 26 and 31-32 are pending in the application. Applicant expressly reserves the right to reclaim the canceled subject matter in a subsequent application.

Claim 17 is currently amended to incorporate the limitations of claim 16, from which it originally depended. Support for this amendment may be found in the claims as originally filed. Claims 22 and 26 are amended to include the composition of claim 17. Support for this amendment may be found in the specification beginning on page 25 line 8 and continuing through to page 26 line 7. Claims 22, 26, 31 and 32 are also amended to correct claim dependencies due to cancellation of claims. Applicants submit that the amendments do not introduce new matter.

Applicants are grateful for the withdrawal of the 35 U.S.C. 112 first paragraph rejections of claims 1, 20, 30-33 and 38 as well as claims 1-17, 20-22 and 26.

CLAIM REJECTIONS

1. Claim Rejections – 35 U.S.C. § 103(a)

1A. Rejection of claims 2-22, 26, 30-34 and 38 under 35 U.S.C. 103(a)

On pages 3-8 of the instant Action, the Examiner has maintained the rejection of claims 2-22, 26, 30-34 and 38 under 35 U.S.C. § 103(a) as being unpatentable over Gordon *et al.* (PCT International Publication WO 00/39130, referred to hereinafter as “Gordon”) in light of Rybak (PCT International Publication WO 01/64197, referred to hereinafter as “Rybak”). In brief, the Examiner alleges that as Gordon discloses the farnesyl transferase inhibitors (FTIs) of instant claims 2-17, and as Rybak discloses therapeutic combinations of anthracyclines and FTIs, it would have been obvious to the skilled artisan to provide a pharmaceutical composition comprising an FTI according to Gordon

and an anthracycline such as doxorubicin. The Examiner further alleges that as FTIs and anthracyclines are believed to exhibit anti-tumor activity, it would be obvious to use a combination of an FTI and an anthracycline to treat nasopharyngeal carcinoma (NPC). The complete details of the Examiner's comments are found on pages on pages 3-8 of the instant Action and are not reiterated in full in this reply.

1B. Amendments to the claims

Claims 2-16, 20-21, 30, 33 and 34 are canceled and claims 17, 22, 26, 31 and 32 are amended in this reply.

1C. Claims 17-19, 22, 26, 31 and 32 are not obvious over Gordon in light of Rybak

Applicants respectfully disagree that the invention of claims 17, 22, 26 and 31-32 is obvious over Gordon in light of Rybak. Applicants submit that cancellation of claims 2-16, 30, 33-34 and 38 renders moot the rejections against these claims.

Applicants again respectfully submit that the Examiner has failed to meet the basic CAFC requirement that an obviousness rejection must be supported by some suggestion in the prior art to create the claimed invention:

[A] proper analysis under §103 requires, *inter alia*, consideration of . . . whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed invention,

In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) (emphasis added).

The Examiner alleges that the combination of Rybak and Gordon make obvious the preparation of and use of a combination of an anthracycline and an FTI to treat NPC. Applicants respectfully disagree.

Applicants first note that neither Gordon nor Rybak teach or suggest Applicants' particular FTI/anthracycline composition recited in instant claim 17. Gordon lists several FTIs but fails to identify the particular FTI of claim 17; Rybak cannot remedy this defect as Rybak also fails to recite the FTI of claim 17. Rybak fails to teach or suggest pairing any other FTIs in combination with anthracyclines except for those recited in

Rybak, a failure Gordon cannot remedy as Gordon fails to recite any FTI/anthracycline combinations at all. Applicants thus respectfully submit that the combination of Gordon and Rybak fail to teach or suggest the pharmaceutical composition of claims 17-19.

Applicants submit that as the combination of Gordon and Rybak fail to teach or suggest Applicants' claimed composition, Gordon and Rybak also fail to teach or suggest the use of Applicants' composition to treat NPC. Thus, the combination of Gordon and Rybak fails to meet the "should" requirement of a proper 103(a) rejection.

As further detailed by the CAFC a "proper obviousness analysis requires consideration of whether the prior art would also have revealed that in so making or carrying out [the claimed invention], those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

Applicants respectfully submit that Rybak and Gordon each fail to provide data demonstrating that the combination of an FTI and an anthracycline actually confer any anti-tumor effect, let alone an anti-tumor effect upon NPC. Applicants again direct the Examiner to instant Figure 1, which elegantly shows that doxorubicin in combination with FTI Compound A results in a greater decrease in cell viability as compared to doxorubicin or Compound A alone.

Absent such teachings in Rybak and Gordon, Applicants respectfully submit the combination of Gordon and Rybak cannot and does not lead the skilled artisan to expect successful treatment of NPC utilizing any combination of an FTI and an anthracycline, let alone Applicants' FTI/anthracycline composition of claims 17-19. Thus, the combination of Gordon and Rybak fail to meet the "expectation of success" requirement of a proper 103(a) rejection.

Applicants again respectfully submit that the Examiner has failed to support his conclusion that two compounds allegedly "known to be useful for the treatment of cancer broadly" can also be used to treat a particular subset of cancer, such as NPC. Applicants submit that the Examiner has failed to provide any reference teaching that an FTI in combination with an anthracycline purported for use against a non-

nasopharyngeal cancer would be efficacious against NPC. Gordon and Rybak recite a number of ras-associated cancers but both fail to recite NPC as a candidate cancer for treatment with an FTI and/or an anthracycline. As such, Gordon and Rybak fail to support the Examiner's allegation that any anti-cancer agent may be used to treat any type of cancer.

As recited in the MPEP at 2143.03, "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)". Applicants submit that the combination of Gordon and Rybak fail to teach or suggest all aspects of Applicants claimed FTI/anthracycline composition and use thereof to treat NPC. Neither Gordon nor Rybak teach the particular FTI/anthracycline composition of claims 17-19. Neither Gordon nor Rybak contemplate the treatment of NPC using FTIs and/or anthracyclines. Thus Applicants submit that as this combination of references fails to teach or suggest all aspects of Applicants method, the references fail to make obvious the instant invention.

In summary of the arguments presented above, Applicants submit that the Examiner has failed to meet all three requirements for a proper 103(a) rejection: the combination of Gordon and Rybak fail to meet the "should make the claimed invention", "expectation of success" and "teach all aspects of the claims" prongs of the obviousness requirement.

1D. Request for withdrawal of rejection of claims 17-19, 22, 26 and 31-32 under 35 U.S.C. § 103(a)

Applicants submit that, for reasons cited above, claims 17-19, 22, 26 and 31-32 are in no way made obvious by Gordon in light of Rybak. Applicants request the reconsideration and withdrawal the rejection of claims 17-19, 22, 26 and 31-32 under 35 U.S.C. § 103(a).

Request for Rejoinder

Applicants respectfully request rejoinder of previously canceled claims 34-36 and 38-40 directed to a kit comprising the FTI/anthracycline combination of claims 17-19. Applicants submit that as the claims were not subject to a restriction earlier in prosecution, claims 34-36 and 38-40 are subject to rejoinder upon the allowance of product claims 17-19. As noted in the MPEP821.04:

[I]f Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined . . . Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance.

Applicants submit that claims 34-36 and 38-40 currently incorporate the limitation of claims because the composition of the kit is the composition of claims 17-19 and uses thereof to treat NPC. Applicants respectfully request the rejoinder of claims 34-36 and 38-40.

Reconsideration of the instant Office Action, entry of the amendments submitted herewith, and allowance of all pending claims are respectfully requested. Prompt and favorable action is solicited.

Respectfully submitted,

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Pamela C Ball

Pamela C. Ball
Agent for Applicant(s)
Reg. No. 53,963

Biomeasure, Incorporated
27 Maple Street
Milford, MA 01757-3650
(508) 478-0144 Telephone
(508) 473-3531 Facsimile